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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,539	04/28/2000	Roy Curtiss III	3116-4355	3756

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Howell & Haferkamp LC
Patents Trademarks Copyrights Unfair Competition
Suite 1400 Pierre Laclede Center
7733 Forsyth Boulevard
Saint Louis, MO 63105-1817

EXAMINER

FIELDS, IESHA P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/560,539

Applicant(s)

CURTISS ET AL.

Examiner

Iesha P Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1,5,9-11 and 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-4,6-8,12-22 and 32-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed September 6, 2001 (Paper No. 11) has been received and entered. In a response mailed August 3, 2001 Applicants were required to elect a single species for examination. Applicants elected bacteria as the microorganism, a plasmid vector, P22Pr as the first control sequence, Ptrc as the second control sequence, araCP_{BAD} as the first activatable control sequence, C2 as the first repressor sequence, pSC ori as the first origin of replication, pUC ori as the second origin of replication, ΔphoPQ as the mutation to attenuate, and a delayed expression of antigen as the type of expression. Therefore claims 1-38 are pending in the instant application, and claims 2-4, 6-8, 12-22, and 32-37 (Group II) to extent of the elected species listed supra are under examination in the instant Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 2, 4, 6-8, 12-22, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. in view of Stocker et al.

The claims are drawn to a regulated antigen delivery system.

Morris et al. (US Patent 5,674,746) teach of a regulated antigen delivery system (RAD). Morris et al. further teach of a plasmid that includes a gene encoding a gene product operably linked to a control sequence, an origin of replication conferring vector replication, where the second origin of replication is operably linked to a control sequence that is repressible by a repressor (See Entire Document).

Morris et al. does not teach of a regulated antigen delivery system wherein the microorganism is a *Salmonella* species.

Stocker et al. (US Patent 4,837,151) teach of a regulated antigen delivery system wherein the microorganism is a *Salmonella* species. Stocker et al. further teach that the composition may be used as a vaccine (See Entire document).

Given that 1) Morris et al. has taught of a regulated antigen delivery system and that 2) Stocker et al. has taught of a regulated antigen delivery system wherein the microorganism is a *Salmonella* species it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a regulated antigen delivery system wherein the microorganism is a *Salmonella* species. One would have been

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motivated to make such a delivery system in view of the teachings of Stocker et al. that such a composition can be used in making vaccine development.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

February 11, 2002


MARK NAVARRO
PRIMARY EXAMINER